

REMARKS

Claims 8-14 and 16-23 are pending. Claim 14 has been amended to recite a temperature range and further clarify that the process does not denature the liquid food product. Support for this amendment is found in the specification on page 15, last paragraph, page 16, first paragraph, page 17, lines 13-23 and in Figs. 2 and 5. Claim 15 has been cancelled. Accordingly, the Applicants do not believe that any new matter has been added.

Rejection--Obviousness-type Double Patenting

Claims 8-23 were rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-11 of U.S. Patent No. 6,511,695. The Applicants submit that this rejection should be withdrawn in view of the arguments presented below with respect to the rejection lodged under 35 U.S.C. §102(e). That is, the claims of the '695 patent are directed to a method that requires denaturation, whereas the claims of the present invention require that the liquid food product not be denatured. Thus, the Applicants respectfully request that this rejection be withdrawn or held in abeyance.

Rejection—35 U.S.C. §112, first paragraph

Claims 14-18 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description. The rejections of claim 15 is moot in view of the cancellation of these claims.

Claims 14 and 16 recite particular numerical ranges the end points of which are clearly exemplified in the specification. Thus, one with skill in the art would recognize that the Applicants were in possession of the invention as it pertains to values within these ranges. The specification precisely describes the metes and bounds of the processes covered by claims 14 and 16 by disclosing or exemplifying the end points of the ranges 25°C and 65°C

(for claim 14) and 100 and 300 mPa (for claim 16). The written description requirement for a claimed genus (in this case the processes involving the temperature range of claim 14 and the pressure range of claim 16), may be satisfied through sufficient description of a representative number of species or by actual reduction to practice, MPEP 2163(II)(3)(ii). The end points of the claimed ranges in this case are representative of the genus of temperature or pressure conditions described in the claims. Thus, the Applicants have shown or reduced to practice a representative number of species which define the end points of the claimed ranges.

Claim 17 was rejected for lack of support for the phrase “for a time period in the order of milliseconds”. Support for this term, and possession of a process that uses a time period in the order of milliseconds, is found in the specification on page 14, lines 7-9, which describes the Emulsifex-C160 dynamic high pressure homogenizer. This homogenizer would provide the time period in the order of milliseconds for processing the liquid food product. By employing this homogenizer, or the Emulsifex-C5 homogenizer described on page 13, line 7, the Applicants demonstrate possession of the subject matter claimed in claim 17 and inherently support the limitations in this claim.

Claim 18 was rejected as lacking support for “a period of 183 milliseconds”. The Emulsifex C160 homogenizer described in the specification on page 14, line 9, allows a constant flow rate under 160 L per hour. This means that each milliliter is submitted to the dynamic high pressure for a period of 183 milliseconds. Thus, by describing this homogenizer, its flow rate and its method of use, the Applicants demonstrate possession of the subject matter of claim 18 and inherently support its limitations.

Rejection—35 U.S.C. §112, second paragraph

Claim 17 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for using the phrase “for a time period in the order of milliseconds”. This phrase does not refer to a time period in the order of seconds (e.g., 5 seconds or 5,000 milliseconds), but to one in the order of milliseconds as exemplified by a process using the homogenizers disclosed in the specification. For example, the Emulsifex C5 homogenizer performs dynamic high pressure homogenization at a rate between 1-5 liters per hour. This means that the passage time of the liquid through the homogenizing valve can be between 1-8 milliseconds per milliliter of liquid. A process using this homogenizer exhibits a time period in the order of milliseconds, not in the order of seconds. The Applicants also note that this same terminology appears in U.S. Patent No. 6,511,695, see claim 1, wherein it was not found indefinite. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. §102

Claims 8-10, 12, 13, 16, 19 and 23 were rejected under 35 U.S.C. 102(b) as being anticipated by Klopp et al., DE 3903648A. The process of Klopp does not anticipate the invention, because the two processes use different kinds of homogenizers. The present invention requires a dynamic high pressure homogenizer, exemplified by the Emulsifex-C5 and Emulsifex C160. On the other hand, Klopp describes a closed container used as a homogenizer containing a valve which creates cavitations by emitting acoustic radiations into the homogenizer. The liquid is circularly shaken into the homogenizer for a certain period of time, varying between 1-20 minutes, but preferably 5 minutes. Clearly, Klopp describes a compression tube which is designed so that the liquid moves therein circularly with a sonic source located within the compression space. Even though different parts of the Klopp device are called a “homogenizer”, the function of those parts is absolutely different. For

example, in Klopp the cavitation is created by an oscillator emerged in the liquid or by overflow borders connected in series on the valve. Thus, Klopp does not disclose a continuous pressurizing circulation system which comprises a dynamic high pressure homogenizer.

Also, the Klopp process does not involve continuously passing a liquid food product through a homogenization valve or disclose other elements of the invention, such as homogenizers having the passage times described in the claims, see e.g., claims 13, 17 and 18.

Moreover, Klopp does not disclose with sufficient specificity the other aspects of the invention, such as treatment of a liquid food product without denaturation or the other limitations in these claims. The Klopp process is directed to inactivating viruses, such as bacteriophages, in culture supernatants and in products worked up from recombinant microorganisms, such as plasma factor VIII and other blood factors, see page 2, 6<sup>th</sup> paragraph. While page 4, line 6, does refer to the milk industry, it does not disclose homogenizing a liquid food product such as milk. Rather this section describes the preparation of solutions freed from viruses, such as starter cultures that may find application in the milk industry. Thus, there is no disclosure of the limitations in claim 19, directed to treatment of milk.

In view of the differences between the homogenizers used by Klopp, in the homogenization conditions and process steps, and the lack of specificity in describing a method for treating a liquid food product, such as milk, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. §102

Claims 8, 10, 12, 13, 19, 20 and 23 were rejected under 35 U.S.C. 102(b) as being anticipated by Mun et al., SU 16660218A. Mun does not anticipate the present invention, because the prior art process uses a different type of homogenization apparatus and the Mun process does not involve recirculation as required by independent claim 8.

The present invention requires the use of a dynamic high pressure homogenizer. However, Mun uses a pasteurization apparatus in which “dynamic pressure is converted to static pressure. . .creating conditions for rupture of the cell membranes of pathogenic flora” (page 2, lines 22-24). Moreover, the Mun process does not involve recirculation (as does the invention), but repetition of the action which causes the mechanical rupture and pasteurization under static pressure. Since the Mun process is different that that of the present invention because it uses a different type of apparatus and does not involve recirculation, the Applicants request respectfully that this rejection now be withdrawn.

Rejection—35 U.S.C. §102

Claims 8-19 were rejected under 35 U.S.C. 102(e) as being anticipated by Paquin et al., US Patent No. 6,511,695. The issue is whether the prior art process for denaturing milk proteins using a high-pressure dynamic homogenizer (e.g., to modify the gellation properties of milk) inherently discloses all the limitations of the claimed process of reducing the presence of microorganisms which also uses high-pressure dynamic homogenization.

These processes are clearly distinct, because the prior art process requires denaturation of milk proteins, while the process of the present invention requires that the liquid food product not be denatured. The present invention selects process conditions that due not result in denaturation, while that of the prior art patent requires conditions that denature milk. For example, while col. 4, lines 1-6 discloses dynamic high-pressure

homogenizers, this equipment is used to process products in water, buffers or salt solutions, or at pHs necessary to obtain a denatured product (col. 3, lines 55-67). For example, claim 1 of the '695 patent requires "a salt concentration ranging from about 2% to about 35% w/w" and the production of a milk concentrate that is distinguishable from the "corresponding non-denatured protein form".

Moreover, with respect to obviousness, there is no suggestion in Paquin et al. for a method for reducing pathogen content of a liquid food product, since this patent is only concerned with modifying the consistency and firmness and viscosity of the gel obtained from milk products. There is simply no suggestion for a method of reducing pathogen content in Paquin et al. and someone skilled in the art would not conclude that modulating or modifying the firmness or consistency of a milk derived composition, without any extensive experimentation, would result in reducing the number of micro-organisms contained therein. Moreover, there is no reasonable expectation of success for the claimed method of reducing pathogen content by the application of high dynamic pressure. Accordingly, the Applicants respectfully submit that this patent would not anticipate or render obvious the claimed invention.

#### Rejection—35 U.S.C. §103

Claims 21 and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Klopp et al., DE 3903648A, in view of Quinet et al., U.S. Patent No. 5,114,733. These claims are directed to reducing microorganism presence in fat or oil products.

Klopp has been discussed above and does not disclose the homogenization conditions and process steps (such as recirculation) of the present invention and does not disclose with sufficient specificity a method for treating a liquid food product, such as milk.

Quinet is cited as disclosing a method involving the pasteurization of oils or fats.

However, it does not disclose the elements missing from Klopp. Therefore the two references in combination do not disclose all the elements of the invention.

Moreover, there is no suggestion in either document for a process that involves high-pressure dynamic homogenization and recirculation at least three times without denaturation of the liquid food product. Thus, even when reading Quinet and Klopp, someone skilled in the art would not have been motivated to combine these two references to obtain the present invention. Furthermore the cited art does not provide a reasonable expectation of success in obtaining a homogenized liquid food product that is not denatured. For example, Quinet, col. 3, lines 19-27, is unconcerned with whether the food product is denatured, since it refers to pasteurizing the salad mixture within a temperature range of 58°C to 98°C for 10 to 30 mins. On the other hand, the present claims inherently require conditions that do not denature the liquid food product, such as the use of a non-denaturing temperature (specification, page 5, third line from page bottom). Accordingly, neither of these documents, alone or in combination, would make obvious the repeated passage of a liquid containing micro-organisms through a continuous pressurizing circulation system at a nondenaturing temperature through a dynamic high pressure homogenizer to reduce the presence of micro-organisms in said liquid food. Therefore, the Applicants respectfully request that this rejection be withdrawn.

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CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Thomas Cunningham", with a long horizontal flourish extending to the right.

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